# UNITED STATES DISTRICT COURT DISTRICT OF CONNECTICUT

Applera Corporation and :
Roche Molecular Systems, Inc.,:
plaintiffs, :

:

v. : 3:98cv1201 (JBA)

:

MJ Research Inc. and Michael : and John Finney, defendants. :

### OPINION ON INEQUITABLE CONDUCT

As a counterclaim and an affirmative defense to plaintiffs' (collectively, "Applera") claims of infringement, defendants MJ Research, Inc., Michael Finney and John Finney (collectively, "MJ") alleged that plaintiffs' patents were unenforceable because Applera engaged in inequitable conduct during the prosecution of the '675, '493, and '610 patents. MJ moved for summary judgment on its unenforceability counterclaim, and the motion was denied in a decision issued on March 28, 2002 [Doc. # 624] (Squatrito, J.). A jury trial was held from March 4 to April 2, 2004, and at that time the Court scheduled a separate bench trial on the inequitable conduct claims. Instead of a bench trial, MJ relied on the witness testimony during the jury trial, the trial

¹On April 2, 2004, the jury returned its verdict, finding that defendants induced infringement of the PCR process patents; directly infringed claim 45 of U.S. Patent No. 5,333,675 and claims 1, 44, and 158 of U.S. Patent No. 5,475,610; and induced infringement of claim 16 of U.S. Patent No. 5,656,493, claims 17, 33, and 45 of the '675 patent, and claims 1, 44, and 158 of the '610 patent.

exhibits, and the earlier summary judgment record.<sup>2</sup>

Pursuant to Rule 52(a) of the Federal Rules of Civil

Procedure, the Court now sets forth its findings of fact and

conclusions of law on defendants' inequitable conduct claim. As

discussed below, the Court concludes that MJ has failed to meet

its burden to prove by clear and convincing evidence inequitable

conduct by Applera before the U.S. Patent and Trademark Office

("PTO").

## I. Background

Defendants argue that Applera breached its duty of candor before the PTO in addressing inventorship and prior art affecting the patentability of the '675 and '493 patents. First, defendants claim that Applera knowingly made false statements and failed to disclose material information to the PTO concerning the inventorship of the '675 and '493 patents in order to deceive the PTO into believing that Dr. Kary Mullis was the sole inventor of the asserted claims of the '675 and '493 patents, in order to remove from consideration Dr. Mullis' prior art PCR process patents, when in fact Dr. Mullis was not an inventor of any of the asserted claims in the '675 and '493 patents. In particular, defendants argue that Applera did not consult with the originally

 $<sup>^2</sup>$ Based on this record, both parties submitted their proposed findings of fact and conclusions of law, <u>see</u> [Docs. ## 971, 1129, 1282, 1292], on which the Court has relied as a guide to both the applicable evidence and the parties' respective legal arguments.

named inventors during the prosecution of the '493 patent, who would have informed Applera that Dr. Mullis had no direct involvement in the development of thermal cyclers, and that Applera failed to inform the PTO that Dr. Mullis never programmed a computer to cycle temperatures.

Second, defendants argue that Applera failed to disclose prior art, including the Techne Kjeldahl Apparatus, the MicRIstar reference, and the HP Spectophotometer, which were prior art against the '675 and '493 patents, and failed to disclose a reference entitled <a href="https://doi.org/10.2007/phi/html/protection-linked-l

#### II. Standard

Applicants for patents have a duty to act in candor, good faith, and honesty in prosecuting their patent application with the PTO. Inequitable conduct involves a breach of this duty, and "includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information," to the PTO, "coupled with an intent to deceive" the PTO. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). Where the "failure to disclose" form of inequitable conduct is alleged, there also must be proof of

"knowledge chargeable to applicant of . . . prior art or information and of its materiality." <u>FMC Corp. v. Manitowoc Co.,</u>

<u>Inc.</u>, 835 F.2d 1411, 1415 (Fed. Cir. 1985). These elements — materiality, intent, and knowledge — "must be proven by clear and convincing evidence." <u>Dayco Products, Inc. v. Total Containment, Inc.</u>, 329 F.3d 1358, 1362 (Fed. Cir. 2003).

Once these thresholds have been established, "the court conducts a balancing test and determines whether the scales tilt to a conclusion that "inequitable conduct" occurred. The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." Critikon, Inc. v. Becton Dickinson Vascular, 120 F.3d 1253, 1256 (Fed. Cir. 1997) (citations omitted).

"Materiality" is defined in 37 C.F.R. § 1.56 ("Rule 56").

Because this regulation was amended during the course of the prosecution of Applera's patent applications, two definitions of "materiality" govern this case. Prior to January 17, 1992, Rule 56 provided:

All such individuals [including inventors, patent attorneys, and patent agents] have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.

37 C.F.R.  $\S$  1.56(a)(1989).

The "reasonable examiner" standard was amended when new

regulations were promulgated on January 17, 1992. The amended rule "more narrowly defined materiality" and was intended to "present a clearer and more objective definition" of what information the PTO considered material to patentability. See Dayco Products, 329 F.3d at 1363 (quoting Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992)). The current version of Rule 56 thus provides:

- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
  - (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
  - (2) It refutes, or is inconsistent with, a position the applicant takes in:
    - (i) Opposing an argument of unpatentability relied on by the Office, or
    - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

37 C.F.R.  $\S$  1.56(b).

Disclosure is required where the materiality of the information is in doubt, because "[c]lose cases should be resolved by disclosure, not unilaterally by the applicant." <u>LaBounty Mfg.</u>,

Inc. v. United States Int'l Trade Comm., 958 F.2d 1066, 1076
(Fed. Cir. 1992).

The element of intent may be proven by either direct or indirect evidence. Hycor Corp. v. Schlueter Co., 740 F.2d 1529, 1540 (Fed. Cir. 1984). For example, "intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application." <a href="Critikon">Critikon</a>, 120 F.3d at 1256 (citation omitted). "Given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, " however, "clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required." Northern Telecom, Inc. v. Datapoint, 908 F.2d 931, 939 (Fed. Cir. 1990); Hupp. v. Siroflex of Am., Inc., 122 F.3d 1456, 1466 (Fed. Cir. 1997). Thus, if the failure to disclose or misrepresentation occurred due to "[s]imple negligence, oversight, or an erroneous judgment made in good faith," the requisite intent element is not satisfied. See Speciality Composites v. Cabot Corp., 845 F.2d 981, 992 (Fed. Cir. 1988). A finding of "gross negligence," likewise, "does not itself justify an inference of intent to deceive." Kingsdown Medical Consultants, Ltd. v. Hollister, 863 F.2d 867, 876 (Fed. Cir. 1988).

#### III. Findings of Fact and Conclusions of Law

### A. Sole Inventorship of Dr. Mullis

The jury found that defendants failed to prove by clear and convincing evidence that Dr. Kary B. Mullis was not the sole inventor of claims 17, 33 and 45 of the '675 patent and claim 16 of the '493 patent. Dr. Mullis invented the polymerase chain reaction process ("PCR") and related processes that are the subject of U.S. Patent No. 4,683,202 and several other patents. While Dr. Mullis originally was not named as an inventor in the prosecution of the '493 and '675 patents, (US patent applications serial numbers 833,368 ("'368 application") and 899,061 ("'061 application")), filed by Cetus in February and August 1986), he was added an inventor in 1990. At that time, during the prosecution of the '675 patent, the other co-inventors submitted declarations to the PTO stating:

The error in not joining Kary Mullis as an inventor arose at the time of filing the parent of the subject application on February 25, 1986. At the time of the filing of the parent of this application, it was thought that a general purpose programmable temperature cycler was new. Accordingly, this is what was originally claimed. The original claims did not recite any subject matter regarding the PCR protocol, and it was not deemed necessary to join Kary Mullis as a joint inventor. The subject matter of the PCR protocol and much of the specification from the Mullis patent U.S. 4,683,202 was included in the subject application for completeness in the description of how to use the invention.

It was discovered on or about December of 1989, that general purpose programmable temperature cyclers were already in the prior art. Soon thereafter, between December, 1989 and February, 1990, Cetus decided to narrow the original broad claims in light of this prior art. Accordingly, the claims were amended in March 1990 to recite the details of the PCR protocol. It then became clear that Kary Mullis had to be joined as a joint inventor since the

recitations in the claims regarding the PCR protocol were his conception. Accordingly, the error in not naming Kary Mullis as a joint inventor arose inadvertently and without deceptive intent.

Declaration by Richard Leath in Support of a Petition to Add a Joint Inventor, April 2, 1990 [PTX 24]; see also Declaration of Larry Johnson in Support of Petition to Add a New Joint Inventor, April 2, 1990 [PTX 23] (concurring with statement by Richard Leath and stating that he "obtained the details of the PCR protocol indirectly from Kary Mullis by conversations with John Sninsky and Randy Saiki, both employees of Cetus."); Declaration of Larry Johnson in Support of Petition to Add a New Joint Inventor, August 23, 1990 [PTX 14] (stating "I believe the error arose because Kary Mullis had no direct connection with the [instrument design] project and was simply forgotten when inventorship was being considered when we wrote the original invention disclosure describing the subject invention to the Cetus legal department."); Declaration of Kary B. Mullis in Support of Petition to Change Inventorship, April 2, 1990 (concurring with statement by Richard Leath and stating that he "communicated information regarding the PCR protocol indirectly to Larry Johnson and Richard Leath through my communications with Norman Arnheim. This information included the reaction mixture, cycle times and temperatures, the reagents needed, and what a machine to automate the process would have been able to do. This information eventually got to Larry Johnson and Richard Leath,

probably through John Sninsky and Randy Saiki who got it from Arnheim.").3

Applera also submitted to the PTO the declaration of John Atwood, who stated that given the criteria Dr. Mullis set forth, "an average instrument engineer, using only his ordinary skills and routine approach, could have put together a system to automate various PCR protocols." See Declaration of John Atwood, June 3, 1991 [PTX 34].

In support of a 1995 Amendment submitted during the prosecution of Application Ser. No. 08/199,505, which led to the issuance of the '493 patent, Dr. Mullis submitted a declaration that described in greater detail the components of the machine he had earlier envisioned for the performance of PCR:

An embodiment of an apparatus for automated PCR temperature cycling that I conceived very early, before the Cetus Instrument Group became involved, included three elements: a metal block with a number of wells, for example 8, for microcentrifuge tubes ("Eppendorf" tubes) of 0.5 ml or 1.5 ml capacity; in physical contact with the block, a Peltier thermoelectric heater/cooler, such as is shown in Figs. 1, 3, and 4 of the '675 patent and described in the specification at columns 7-11 of that patent; and a user-

³Although these declarations were not resubmitted to the PTO during the reexamination of the '675 patent, Applera was under no duty to do so, because a patent examiner has access to the patent file, and is expected to read the prosecution histories of the prior related proceedings. See, e.g. MPEP \$ 2235(c) (stating that "the reexamination file and patent file will be kept together, from initial receipt until the reexamination is assigned to an examiner for determination. At this point, the patent file will be charged to the examiner assigned the reexamination file and will be kept in the examiner's room until the proceeding is terminated.").

programmable microprocessor controller for the Peltier device, permitting a user to program the apparatus to carry out PCR reactions. At the time I conceived of the PCR process, I had in my laboratory at Cetus a Hewlitt Packard spectrophotometer that was equipped with a Peltier device to heat and cool the sample cuvette, plus a microprocessor controller, programmable by a simple keyboard, for control of the Peltier device. It occurred to me that a Peltier device would perform the required heating/cooling for PCR, would be inexpensive and could be controlled in a programmable fashion. I believe that I may have, and probably did, relate my conception to one or more co-workers at Cetus. I am aware that Corey Lewinson recalled that I told him of my conception before we had any automated apparatus in the laboratory. His recollection confirms my memory that he was a likely candidate for a co-worker I would have told.

For PCR reactions with stable enzyme and temperatures that do not denature the polymerase, I considered that an apparatus with the three elements described above in paragraph 5 would completely automate PCR reactions.

Given the parameters of the PCR process that I had worked out prior to filing my first patent application and that I reported in Examples 1-5 of my '202 patent, given my conception of automated PCR, also reported in my March 1985 patent application, and given my conception of heating and cooling a metal block with a number of wells using a commercially available Peltier device and a programmable microprocessor controller, I considered it to be a simple job for an instrument engineer to put together a working temperature cycling apparatus for PCR.

In fact, a thermal cycler of that description was later built for me at my request at Cetus in the spring of 1986. It was assembled in a short time. As I recall, the block was aluminum and had recesses for 8 Eppendorf tubes. The Peltier device and programmable controller were off-the-shelf components. I tested the device and used it for PCR - it successfully performed PCR reactions on numerous occasions. At the time I requested that the apparatus be built, I had not read U.S. patent application Serial No. 833,368, filed Feb. 25, 1986, for which I was not yet listed as an inventor; and I was unaware of any thinking of others, including named co-inventors on the '675 patent, regarding consideration or use of a Peltier device.

Declaration of Kary Mullis, February 18, 1994 [PTX 64] at ¶¶ 3-

8.4

Based on the evidence on which the jury found that defendants failed to prove that Dr. Mullis was not the sole inventor of the asserted claims of the '675 and '493 patents, the Court concludes that defendants have not proved the existence of any misrepresentations regarding inventorship. The declarations presented to the PTO acknowledge the initial failure to name Dr. Mullis as an inventor, explain the reasons for this omission, and explain why Dr. Mullis was believed to be the sole inventor of the asserted claims. The Patent Office thus had before it the relevant information necessary to decide the patentability of the asserted claims of the '675 and '493 patents, including facts that defendants here use to cast suspicion on Applera's actions (for example, that Dr. Mullis was not included on the original invention disclosure forms and that Dr. Mullis did not speak directly with the engineers earlier named as inventors). Applera, moreover, acknowledged in its 1995 Amendment to the '493 patent application that it understood that one of the originally

<sup>&</sup>lt;sup>4</sup>The 1995 Amendment, which Dr. Mullis's Declaration accompanied, further disclosed that "[i]nasmuch as Dr. Mullis was not originally named as an inventor on Ser. No. 833,368 (filed 2/25/96), the earliest application as to which the instant application claims priority and which discloses a Peltier device, it is understood that at least one of the Cetus instrument persons originally named as inventors also independently conceived of using a Peltier device in a PCR instrument. The significant fact, however, is that Dr. Mullis had that conception as well." Amendment to Application Ser. No. 08/199,505 [PTX 63] at 9.

named inventors on the invention disclosure regarding the "Son of Cycle" machine independently conceived of using a Peltier device in a PCR instrument.

Defendants have also failed to prove by clear and convincing evidence that Applera intended to deceive the PTO. At best, defendants' references to deposition testimony of the engineers would indicate that it may have been prudent for Applera to return to the engineers in 1995 to determine whether they would verify Dr. Mullis' 1995 declaration, which explained in detail for the first time his conception of automation using a metal block and a Peltier device. Such evidence is plainly insufficient to meet defendants' burden. See, e.g. Speciality Composites, 845 F.2d at 992 (evidence of negligence does not satisfy the intent element). First, Dr. Mullis' declaration need not be viewed as inconsistent with the omission of his name from the "Son of Cycle" invention disclosure form, because one of the

<sup>&</sup>lt;sup>5</sup>At trial, Dr. Mullis testified that he conceived of automating the PCR process using a Peltier device, a metal block, and a microprocessor, and asked the Cetus instrument group to build such a device for him, which became known as "Son of Cycle". See Trial Tr. [Doc. # 1100] at 178:23-179:16. Fred Faloona, who worked for Dr. Mullis in the Cetus DNA synthesis lab, corroborated this testimony, and stated that at the time Dr. Mullis conceived of this idea, there were no other instruments automating the PCR process. See Trial Tr. [Doc. # 1105] at 877:5-10. Defendants elicited no conflicting testimony on this issue at trial. While Joseph Widunas testified in a deposition, which was not introduced into evidence at trial, that he conceived of using a Peltier device, such testimony need not be viewed as inconsistent with Dr. Mullis's testimony, as discussed above.

named Cetus inventors may have conceived of using a Peltier device independently from Dr. Mullis and at a later time.

Applera made this argument to the PTO during the prosecution of the '493 argument, and it is possible to infer that the PTO agreed that there was no inconsistency, as the '493 patent issued. While intent can be inferred from indirect evidence, here the record is devoid of evidence that Applera knew of information inconsistent with Dr. Mullis' claim of inventorship, and intended to deceive the PTO by intentionally failing to disclose this information.

Defendants also argue that the fact that Dr. Mullis did not himself program a computer to cycle temperatures was material to the inventorship issue, and Applera's failure to disclose this information constitutes inequitable conduct. At trial, Dr. Mullis testified that writing the computer program needed to run the PCR heating and cooling steps was not itself inventive. See Trial Tr. [Doc. # 1099] at 250 ("[T]he actual translation of commands that say heat to a certain temperature . . . nobody would consider that, I don't think, creative.").

Defendants have failed to meet their burden of demonstrating that writing the computer code necessary to implement the PCR processing steps conceived by Dr. Mullis was material to patentability. Dr. Mullis testified, for example, that he "wrote down the steps like in English saying here is what you're

supposed to do, and the people downstairs . . . actually write the [code]," Trial Tr. at 249:13-19, which supports the conclusion that he was the sole inventor of the asserted claims. Defendants have presented no evidence that the computer code itself is an inventive aspect of the patent, and no basis for finding that the claimed inventor's failure to write the programming code would "compel a conclusion that a claim is unpatentable." See 37 C.F.R. § 1.56(b). In the absence of this showing of materiality, the failure to disclose this information does not rise to the level of inequitable conduct.

#### B. Prior Art

# 1. '675 and '493 patents

Three days prior to the start of trial, defendants raised for the first time a claim of inequitable conduct based on prior art against the '675 and '493 patents that Applera failed to disclose to the PTO — the Techne Kjeldahl Apparatus, the MicRIstar/Pro-star Controller, and the HP Spectrophotometer. These claims are both untimely and fail on their merits. During the reexamination of the '675 patent, MJ sought to have the examiner consider both the Techne Kjeldahl Apparatus and the MicRIstar reference as prior art. The examiner refused, concluding with regard to the Techne apparatus, that "the publication 'Advertisement by Techne for Kjeldahl apparatus' does not raise a new question of patentability as to claims 2, 5, 6,

11-13, 15-38, 40-46, 48-57 because it has not been shown to be prior art. This publication has no date." Order Granting/Denying Request for Examination, Nov. 7, 1997 [PTX 45] at 3. With regard to the MicRIstar reference, the examiner found that "the Micristar Operational Guide does not raise a new question of patentability as to claims 2, 5, 6, 11-13, 15-38, 40-46, 48-57 because it has not been shown to be prior art. copyright date of 1986 is not prior to the effective date of the patent which is February 25, 1986." Id. MJ made a second request for reexamination, including two new claimed prior art publications regarding the Techne Kjeldahl Apparatus, and restating its argument that the MicRIstar reference constituted prior art. See Second Request for Reexamination of U.S. Patent No. 5,333,675 Feb. 22, 1993 [PTX 46]. The Examiner reaffirmed his earlier decision that these items were not shown to be prior art.

Defendants have not presented any new evidence suggesting that these items were in existence prior to the effective date of the patents in suit. 6 Moreover, even if the Techne apparatus and MicRIstar reference could be considered as prior art, MJ has offered no evidence from which to conclude that a "reasonable"

<sup>&</sup>lt;sup>6</sup>Defendants argue that Applera knew that the PTO was wrong when it found that these devices were not prior art. Defendants have not presented any evidence demonstrating how the examiner erred or how Applera would know that the devices were in existence prior to the patents' effective date.

examiner" would consider this prior art important in deciding whether to allow the application to issue as a patent, and no evidence from one skilled in the art that these items establish a prima facie case that the asserted claims of the '675 and '493 patents are unpatentable as obvious in view of the prior art. As such, defendants have failed to prove by clear and convincing evidence the materiality of the Techne Kjeldahl Apparatus or the MicRIstar reference.

Defendants also argue that Applera committed inequitable conduct during the prosecution of the '675 and '493 patents, and during the reeximination of the '675 patent, by failing to fully disclose to the PTO the HP Spectrophotometer, the accompanying Peltier heater, and how the device worked. Applera, however, disclosed the existence of the HP Spectrophotometer and the Peltier heater to the PTO in Dr. Mullis' 1995 declaration, which accompanied an amendment submitted during the prosecution of the

<sup>&</sup>lt;sup>7</sup>MJ argues that the "materiality of the Techne Kjeldahl Apparatus cannot be questioned" because "this Apparatus includes a metal block for holding test tubes (a key feature Applera now relies on to argue patentability), and a means for heating (active) and cooling (passive) under computer control." MJ's Proposed Reply Findings of Fact and Conclusions of Law on Inequitable Conduct [Doc. # 1129] at ¶ 18. MJ also argues that because the "MicRIstar device is a microprocessor-based temperature controller," its "materiality to the '675 patent cannot be seriously questioned." <u>Id</u>. at ¶ 24. Although defendants were permitted to offer evidence in support of their inequitable conduct claims at the time of the trial, they did not do so, and have included no citations to record evidence on the Techne Kjeldahl Apparatus or MicRIstar device other than their reexamination request.

'493 patent, and which was submitted during the reexamination of the '675 patent. In his declaration, Dr. Mullis explained that the idea of using a metal block and a Peltier device to perform the automated heating and cooling functions of the PCR process came to him because he had in his lab a "Hewlitt Packard spectrophotometer that was equipped with a Peltier device to heat and cool the sample cuvette, plus a microprocessor controller, programmable by a simple keyboard, for control of the Peltier device." Mullis Declaration [PTX 64] at 3.

At trial, Dr. Mullis testified that he never tried to perform PCR on the HP spectrophotometer, but that "it might have done fine," although he did not think that it "had a device on it that said you do this over and over again. If I wanted to do something over and over again, I would probably have had to punch in new instructions for it every time it did it." Trial Tr.

[Doc. # 1100] at 207:11-208:5. Fred Faloona similarly testified that the "problem" with the HP spectrophotometer was that

it didn't allow enough temperatures to be set, so you would have to keep running it again and again, as well as the cuvettes tended to hold a lot more volume than we really wanted to do in a given reaction . . [I]t wasn't really useful [for programming times and temperatures to perform a PCR reaction] because it only allowed a couple of temperatures to be set, so you couldn't repeat over and

<sup>&</sup>lt;sup>8</sup>As Dr. Mullis explained at trial, the spectrophotometer was a machine for measuring the "optical density or the absorption of light at different frequencies" as a function of temperature "as they went through a little cuvet full of some liquid." Trial Tr. [Doc. # 1100] at 181:24-182:4.

over, as well as the fact that it really only allowed for one sample to be heated and cooled.

Trial Tr. [Doc. # 1105] at 870:20-871:7.

The testimony at trial, therefore, showed that Dr. Mullis never attempted to use the HP spectrophotometer to perform PCR, that the device was not capable of performing the multiple cycles of heating and cooling that are part of the PCR protocol, and that the device was unable to run more than one sample at a time. As all of the asserted claims of the '493 and '675 patents require programming for multiple temperature cycles, and two of the asserted claims (claim 16 of the '493 patent and claim 45 of the '675 patent) require that the metal block contain a plurality of recesses, there are significant differences between the spectrophotometer and what was claimed in the '493 and '675 patents. Defendants have presented no evidence from one skilled in the art from which the Court could conclude that the HP spectrophotometer was material to patentability of the '493 and '675 patents. Moreover, defendants have failed to present any

<sup>&</sup>quot;See '675 Patent [PTX 5] (claims 17, 33, and 45 feature means "for heating and cooling said container to or at any of a plurality of temperatures."); Claim Construction of Disputed Terms in U.S. Patents 5,333,675, 5,656,493, and 5,475,610 [Doc. #715] at 25 (construing claim 16 of the '493 patent to require, inter alia, "a computer programmed to vary the temperature of a heating and cooling system in accordance with multiple cycles of the steps of thermal denaturation of double-stranded DNA, primer hybridization to a single-stranded DNA, and template-dependent primer extension by a DNA polymerase." (internal quotation omitted).

evidence of Applera's intent to deceive. Applera informed the PTO about the HP spectrophotometer and its role in Dr. Mullis' conception of PCR. There is no basis for inferring a bad faith motive in Applera's failure to inform the PTO that the spectrophotometer may have been able to perform PCR, because Dr. Mullis never attempted to perform PCR on the device.

### 2. '610 patent

Finally, defendants argue that Applera failed to disclose a reference entitled Thermal Gradients in Microtritation Plates, Effects on Enzyme-Linked Immunoassay, Journal of Immulogical Methods, Diane G. Oliver et al., Vol, 42, pp. 195-210 (1981) ("Oliver Reference"), which predates the '610 patent and, defendants contend, teaches the algorithm of claim 1. The Oliver reference established a means to calculate the temperature of the fluid in a sample tube based on the temperature of its environment, and at trial, defendants' expert testified that this reference rendered claim 1 of the '610 patent obvious and unpatentable. See Testimony of Shariar Motakef, Trial Tr. [Doc. # 1109] at 2496:19-22, 2497:16-2498:11. The jury decided against defendants at trial, however, finding that defendants failed to prove that claim 1 of the '610 patent was "obvious" in view of this prior art.

Defendants have not met their burden of proving by clear and convincing evidence that Applera's failure to disclose the Oliver

reference constituted inequitable conduct, because the Oliver reference has not been shown to be material to patentability. The Court discounts Dr. Motakef's testimony because although he was an expert in the semiconductor field, he was not shown to be skilled in the art of thermal cycler design, as he acknowledged at trial that he had never designed a thermal cycler for use in PCR, and that he considered a person to be skilled in the art to be an engineer "who works in a team who has some experience with thermal cyclers." See Trial Tr. [Doc. # 1109] at 2500:19 - 2501-The Oliver reference, moreover, dealt with different subject matter than the thermal cycler claimed in the '610 patent, as it examined the lack of temperature uniformity in wells of microtritation plates, which used still air and forced air incubators to heat liquid samples. 10 Defendants' expert offered no testimony that compared claim 1 of the '610 patent, when viewed as a whole, to the Oliver reference. Instead, defendants' expert noted some similarities between the algorithm in the Oliver reference and in claim 1, and between thermal cyclers and

<sup>10</sup>Claim 1 of the '610 patent features a means for controlling the temperature of the thermal cycling machine by determining the temperature of a liquid sample mixture as a function of the temperature of the sample block over time. It features a metal block, and did not use air as the means to change the temperature. See Claim Construction [Doc. # 715] at 25, 30. Claim 1 uses the temperature of the block, measured by a sensor, to determine the temperature of the sample, while the experiment conducted by Diane Oliver used a probe to measure the temperature of the sample. See Trial Tr. [Doc. # 1109] at 2510:21-2511:

microtitration plates, and testified that it would have been "obvious to try" to combine preexisting thermal cyclers with the Oliver reference. See Trial Tr. [Doc. # 1109] at 2496:3-18, 2508:16-21.11 "Obvious to try," however, is the incorrect test for patent validity. See In re Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995) ("'Obvious to try' has long been held not to constitute obviousness.").

Finally, defendants have failed to prove by clear and convincing evidence any intent to deceive the PTO by not disclosing the Oliver reference. Defendants state only that the article came from the files of Dr. Fenton Williams, an Applera employee, but have pointed to no testimony about his degree of familiarity with the Oliver reference, his precise role in developing the claimed invention, or his view of the materiality of the Oliver reference. The mere suggestion of knowledge of the prior art cannot meet defendants' heavy burden of proving intent.

Trial Tr. [Doc. # 1109] at 2508:16-21

<sup>11</sup>On Cross examination, Mr. Motakef testified as follows:

Q. Now as of '91, your opinion was that you wouldn't have known if that combination that you have described would work, but that in your opinion it would have been obvious to try that combination, correct?

A. Yes.

 $<sup>^{12}</sup> Fenton$  Williams is listed as one of ten joint inventors on the '610 patent. See [PTX 7].

### IV. Conclusion

For the foregoing reasons, the Court concludes that defendants have failed to prove that Applera engaged in inequitable conduct.

IT IS SO ORDERED.

/s/

Janet Bond Arterton, U.S.D.J.

Dated at New Haven, Connecticut, this 29th day of March, 2005.